

## REMARKS

### I. General

Claims 32, 57-74, 76-77 and 78-79 and 82-83 are pending in the application. Claims 75, 80 and 81 are to be canceled. The issues in the Office Action mailed May 3, 2006 are as follows:

- Claims 32, 57-61 and 77 were rejected under 35 U.S.C. § 103(a) as being obvious over US Patent No. 5,353,788 in view of US Patent No. 6,000,395.
- Claims 62-66, 68, 69, 70, 71, 73-76 and 79-83 were rejected under 35 U.S.C. § 103(a) as being obvious over US Patent No. 5,353,788 in view of US Patent No. 6,000,395.

Applicant hereby traverses the outstanding rejections and objections and requests reconsideration and withdrawal in light of the remarks, and amendments contained herein.

### II. Claim Rejections 35 USC 103(a).

Claims 32, 57-61 and 77 were rejected under 35 U.S.C. § 103(a) as being obvious over US Patent No. 5,353,788 in view of US Patent No. 6,000,395

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art cited must teach or suggest all the claim limitations. See M.P.E.P. § 2143.

Claims 32, 57-61 and 77 include the limitation of a processor determining the patient's sleep stage based at least in part on a received EEG signal and a gas delivery device in communication with said breathing mask, the gas delivery device delivering gas to the patient based on the processor determination of said patient's sleep stage.

The combination of Miles and Brown, even if proper, would fail to yield sleep stage determination and a gas delivery device controlled by a processor and to adjust the delivered gas based on the processor determination of sleep stage.

Contrary to Examiner's position, it is submitted that computer (25) in Miles does not determine patient sleep stage. Sleep stages are demarcated by significant polysomnographic characteristics that distinguish the boundaries of the sleep stages. Sleep stage 1 - a stage of non-REM (NREM) sleep occurring after wake. Its criteria consist of a low-voltage EEG with slowing to theta frequencies, alpha activity less than 50%, EEG vertex spikes, and slow rolling eye movements; no sleep spindles, K-complexes, or REMS. Stage 1 normally assumes 4-5% of total sleep. Sleep stage 2 - a stage of NREM sleep characterized by sleep spindles and K complexes against a relatively low-voltage, mixed-frequency EEG background; high-voltage delta waves may comprise up to 20% of stage 2 epochs; usually accounts for 45-55% of total sleep time. Sleep stage 3 - a stage of NREM sleep defined by at least 20 and not more than 50% of the period (30 second epoch) consisting of EEG waves less than 2 Hz and more than 75 uV (high - amplitude delta waves); a "delta" sleep stage; with stage 4, it constitutes "deep" NREM sleep; appears usually only in the first third of the sleep period; usually comprises 4-6% of total sleep time. Sleep stage 4 - all statements concerning NREM stage 3 apply to stage 4 except that high-voltage, slow EEG waves, cover 50% or more of the record; NREM stage 4 usually takes up 12-15% of total sleep time. Somnambulism, sleep terror, and sleep-related enuresis episodes generally start in stage 4 or during arousals from this stage. Sleep Stage REM - the stage of sleep found in all mammal studies, including man, in which brain activity is extensive, brain metabolism is increased, and vivid hallucinatory imagery, or dreaming occurs (in humans). Also called "paradoxical sleep" because, in the face of this intense excitation of the CNS and presence of spontaneous rapid eye movements, resting muscle activity is suppressed. The EEG is a low-voltage, fast-frequency, non alpha record. Stage REMS is usually 20-25% of total sleep time.

As neither *Miles* nor Brown teaches or suggests at least this feature, Applicant respectfully asserts that claims 32, 57-61 and 77 are patentable over the 35 U.S.C. § 103 rejection of record.

III. Claim Rejections 35 USC 103(a).

Claims 62-66, 68, 69, 70, 71, 73-76 and 79-83 were rejected under 35 U.S.C. § 103(a) as being obvious over US Patent No. 5,353,788 in view of US Patent No. 6,000,395.

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art cited must teach or suggest all the claim limitations. See M.P.E.P. § 2143.

Claim 62, 73 and 79 require a processor in communication with said at least one EEG sensor, said processor determining said patient's sleep stage based at least in part on a signal received from said at least one EEG sensor; and a gas delivery device in communication with said mask, said gas delivery device changing a delivered air pressure to said patient based on a sleep stage determination by said processor. Applicant respectfully asserts that claims 62-66, 68-71 and 73-76 are patentable over the 35 U.S.C. § 103 rejection of record.

Contrary to Examiner's position, it is submitted that computer (25) in Miles does not determine patient sleep stage. Sleep stages are demarcated by significant polysomnographic characteristics that distinguish the boundaries of the sleep stages, as detailed above.

Regarding claim 71, it is submitted that the combination of Miles and Brown, even if proper would fail to yield a mask having a perimeter surface provided with a thermally sensitive material, and wherein the system adjusts a gas pressure based on a processor determination of an air leak as indicated by a change in said thermally sensitive material. Applicant respectfully asserts that claim 71 is patentable over the 35 U.S.C. § 103 rejection of record.

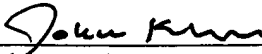
IV. Conclusion

In view of the above remarks and amendment, Applicant believes the pending application is in condition for allowance.

Application No. 09/465,054  
Reply to Office Action of May 16, 2006

Respectfully submitted,  
Compumedics Limited, BY ITS ATTORNEYS

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